



July 10, 2009

Docket No. APHIS 2008-0093
Regulatory Analysis and Development, PPD
APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

Via Overnight Mail and Facsimile: 301-734-8934

Re: R-CALF USA's Third Supplemental Comments in Docket No. APHIS-2008-0093: Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Meat, Meat Byproducts, and Meat Food Products Derived From Bovines 30 Months of Age or Older

Dear Administrator:

R-CALF USA submits these third supplemental comments regarding Docket No. APHIS-2008-0093: Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Meat, Meat Byproducts, and Meat Food Products Derived From Bovines 30 Months of Age or Older ("OTM Rule") to ensure that the U.S. Department of Agriculture's ("USDA's") Animal and Plant Health Inspection Service ("APHIS") is informed about the June 2009 issuance by the European Union's ("EU's") Commissioner for Health of the *Preliminary Report on the monitoring and testing for the presence of transmissible spongiform encephalopathies (TSEs) in the EU in 2007* (hereafter "2007 EU Report").¹

I. INTRODUCTION

The 2007 EU Report provides valuable statistical data concerning the status of the EU's monitoring and testing program for bovine spongiform encephalopathy ("BSE") and other transmissible spongiform encephalopathies ("TSEs"). When these EU data and their results are compared to and contrasted with the monitoring and testing program (hereafter "testing program") that Canada practices for BSE, it is abundantly clear that Canada's BSE testing program is woefully inadequate to: 1) reliably determine the prevalence and evolution of BSE in Canada; and, 2) protect the food supply, both in Canada and the U.S., from contamination by beef from BSE-infected animals.

¹ See Preliminary Report on the monitoring and testing for the presence of transmissible spongiform encephalopathies (TSEs) in the EU in 2007 (hereafter "2007 EU Report"), European Union, Directorate-General for Health & Consumers, 2009, attached hereto as Attachment A. available at http://ec.europa.eu/food/food/biosafety/bse/annual_reps_en.htm.

II. CANADA'S BSE EXPERIENCE WHEN COMPARED TO AND CONTRASTED WITH THE RESULTS OF THE 2007 EU REPORT DEMONSTRATE THAT CANADA'S BSE RISK FAR EXCEEDS ANY REASONABLE DETERMINATION OF ACCEPTABLE RISK

A. Canada's Voluntary BSE Testing Program Fails To Target Subpopulations Of Cattle That Are Likely To Be Highly Susceptible to BSE, As Evidenced In Subpopulations Of Cattle Tested In The EU.

In addition to testing BSE suspects, the EU's mandatory testing program involves active testing of healthy slaughtered cattle and cattle with an epidemiological link to known BSE cases.² The EU defines "active monitoring" as the testing of risk animals, healthy slaughtered animals and culled cattle; and it defines "passive surveillance" as the testing of animals reported as official BSE suspects.³ The EU found that 91 percent of positive BSE cases were detected under active monitoring while only 9 percent were detected by passive surveillance.⁴

Canada's voluntary testing program cannot be justified given Canada's worsening BSE outbreak. The EU recognized the necessity of mandatory testing to adequately protect its domestic cattle herd from the ongoing spread of BSE and protect consumers against the introduction of BSE-infected cattle into the human food supply. The 2007 EU Report reveals that until 2006, Sweden was an outlier among EU Member States as it conducted only random sampling for BSE. Sweden, unlike Canada, had not experienced any outbreaks of BSE prior to 2006 while it conducted only random BSE testing.⁵ However, following its first BSE outbreak in March 2006, Sweden took responsible action to protect its citizens and its cattle herd by following the EU requirements for testing healthy slaughtered cattle.⁶ Member States of the EU are required to test all cattle slaughtered for human consumption over the age of 30 months and all high-risk cattle over the age of 24 months, unless an animal is a BSE suspect, in which case no age limits apply.⁷

It is unconscionable that USDA continues to deny the U.S. cattle herd and U.S. consumers a level of protection against Canada's BSE problem comparable to the protection the EU accords its respective cattle herd and citizens, particularly when the EU has responsibly documented the evolution of its BSE outbreak with sufficient scientific data to distinguish trends regarding the effectiveness of its mitigation measures and Canada has not. USDA has long been negligent in its statutory duty to protect both livestock and consumers against the introduction of BSE, through its action of allowing the continual importation of Canadian cattle and beef that are subjected to Canada's inadequate BSE prevention, protection, and testing programs.

² See 2007 EU Report, at iii.

³ See *id.*, at 1, 7.

⁴ See *id.*, at 1.

⁵ See *id.*, at 16.

⁶ See *id.*, at 3.

⁷ See *id.*, at 5 (note, however, that Germany and Spain require the testing of all healthy slaughtered cattle over the age of 24 months, *see id.*, at 8).

1. The EU experience indicates that the failure of Canada and the U.S. to test seemingly healthy Canadian cattle at slaughter likely is resulting in the introduction of BSE-infected cattle into the human food supply.

Under the EU's 2007 active monitoring program that detected a total of 159 positive BSE cases, 45 of those positive BSE cases were detected in healthy slaughtered cattle.⁸ This means that nearly 30 percent of all positive BSE cases detected through active monitoring were in healthy animals destined for the human food supply; and because of the EU's testing program, those infected animals were not converted to human food. Moreover, the EU found that the rate of BSE positives in healthy slaughtered cattle was .05 cattle per 10,000 cattle tested, meaning that 5 BSE-positive cattle were detected for each 1 million healthy cattle slaughtered.⁹

In sharp contrast to the EU testing program, Canada does not target healthy slaughtered cattle. Instead, Canada's testing program "targets animals at highest risk of being infected by BSE."¹⁰ The EU experience indicates that because Canada does not test healthy slaughtered cattle – despite finding a significant number of BSE cases in testing of high-risk animals born long after implementation of a ban on ruminant protein in ruminant feed, it is allowing perhaps significant numbers of BSE-infected cattle to enter the human food supply, and the U.S. likely is allowing meat from BSE-infected Canadian cattle to be imported into the United States for U.S. consumption. In addition, because the U.S. does not require testing of Canadian cattle imported into the U.S. for slaughter, the U.S. is allowing perhaps significant numbers of BSE-infected cattle to directly enter the U.S. food supply.

2. The EU experience indicates that the failure of Canada and the U.S. to test cattle with an epidemiological link to known BSE cases may result in the introduction of BSE-infected cattle into the U.S. food supply.

Under the EU's active monitoring program, the EU targets birth cohorts (cattle born in a herd within 1 year before or after the birth of a BSE case) and feed cohorts (cattle reared together with a BSE case during the first year of their life).¹¹ In 2007 the EU detected one BSE-positive case in an animal that was a birth or feed cohort from among only 1,471 cohorts tested, indicating a rate of detection among birth and feed cohorts that should be considered quite high – a rate of 6.8 BSE-positive cattle per 10,000 cohorts tested.¹²

In sharp contrast to the EU testing program, Canada does not target birth or feed cohorts for testing, and substantial numbers of such cohorts have and are entering the human food supply and have and likely are being exported to the United States.¹³ The EU experience indicates that

⁸ See 2007 EU Report, at 27, 29.

⁹ See *id.*, at 27.

¹⁰ Surveillance Objectives, Canadian Food Inspection Agency (hereafter "CFIA"), available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/infoe.shtml#ris>.

¹¹ See 2007 EU Report, at 4.

¹² See *id.*, at 28.

¹³ See Letter from R-CALF USA Board President R.M. Thornsberry, D.V.M., to former Agriculture Secretary Ed Schafer, August 7, 2008 ("The CFIA report also indicates that CFIA continues to *not test* birth and/or feed cohorts of known BSE cases."); see also R-CALF USA's Second Supplemental Comments in Docket No. APHIS-2008-0093, June 2, 2009, at 5, 6 (describing the number of BSE cohorts that had been exported from Canada).

because Canada and the U.S. fail to test cohorts from BSE-positive Canadian cattle, BSE-positive cattle are likely entering the human food supply and the actual prevalence of BSE cases in Canadian cattle is being understated.

B. Canada's High Rate Of BSE Detection Combined With Its De Minimis Testing Program Demonstrates That Canadian Cattle And Beef From Canadian Cattle Harbor An Unacceptable Risk For BSE And Should Not Be Imported Into The United States.

Canada's BSE testing program targets only cattle at highest risk for being infected with BSE¹⁴ – which includes the subpopulations of cattle that the EU describes as “risk animals.”¹⁵ In 2008 Canada tested only 48,804 cattle.¹⁶ Based on Canada's estimated adult herd size of approximately 6 million head, Canada is annually testing only about 0.8 percent of its adult cattle population. This rate of testing in relation to Canada's adult herd size is far below the rate of testing conducted on risk animals in 27 of the 28 European countries included in the 2007 EU Report.¹⁷ And yet, Canada detected the same number of BSE-positive cases in 2008 as did Germany in 2007 – a country considered a high risk for BSE with a total of 415 cases – and it detected more BSE cases in 2008 than did 21 of the 28 European countries listed in the 2007 EU Report, including more cases than Belgium, Italy and the Netherlands, all of which are considered a high risk for BSE with 133, 144, and 84 total BSE cases, respectively.¹⁸

Equally alarming is the fact that Canada's 2008 detection ratio of 0.82 BSE-positive cases per 10,000 head tested¹⁹ is higher than the 2007 ratio for the testing on emergency slaughtered cattle in the entire EU;²⁰ higher than the 2007 ratio for the testing on cattle with clinical signs at ante-mortem inspection in the entire EU;²¹ higher than the 2007 ratio for the testing on fallen stock in the entire EU;²² and higher than the 2007 ratio for the testing on *all* risk cattle in the entire EU.²³

With 17 cases of BSE detected in Canadian-born cattle under Canada's de minimis testing program, which is demonstrated to be woefully inadequate based on Canada's startling testing results, USDA should immediately prohibit all imports of Canadian beef and cattle until Canada implements a mandatory testing program that targets each subpopulation of cattle known to be at risk for BSE and allows sufficient time to lapse to effectively evaluate test results and scientifically estimate the actual prevalence of BSE in Canadian cattle. The extrapolation of EU

¹⁴ See *supra*, at 3.

¹⁵ See 2007 EU Report, at 7 (the EU defines risk animals as fallen stock, emergency slaughtered animals and animals with clinical signs at ante-mortem inspection).

¹⁶ See BSE Enhanced Surveillance Report, Canadian Food Inspection Agency, updated May 25, 2009, available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/surve.shtml#num>.

¹⁷ See *id.*, at 13 (only Romania tested at a lower rate, but Romania has never detected BSE in its cattle herd (*see id.*, at 16)).

¹⁸ See *id.*, at 16.

¹⁹ Calculation based on Canada's detection of 4 BSE-positive cases among the 48,804 cattle tested in 2008.

²⁰ See *id.*, at 23.

²¹ See *id.*, at 24.

²² See *id.*, at 25.

²³ See *id.*, at 26.

data to Canada's disease circumstance clearly reveals that the risk of introducing BSE into the U.S. from Canada is unacceptable.

C. While Comprehensive EU Testing Data Demonstrate That The Prevalence Of BSE Is Decreasing In The EU, The Scant Data Available In Canada Suggest That Canada's BSE Prevalence Is Worsening.

The 2007 EU Report contains scientific data that justify the EU's assertion that it has successfully begun to control its BSE outbreak. The 2007 EU Report documents the EU's observation of "[a] favourable evolution (increasing trend)" in the average age of positive BSE cases found in risk animals.²⁴ In other words, when the long incubation of BSE is considered, the fact that the average age of BSE positive cases in the EU is increasing is an indication that the prevalence of BSE in young EU animals is beginning to decrease. This trend, then, indicates that the EU's BSE mitigation measures are having a positive effect on the EU's long-term BSE outbreak.

The 2007 EU Report reinforces further the EU's conclusion that an increased average age of BSE-positive cattle indicates that a country's mitigation measures are effective – and vice versa – by explaining that:

[D]ifferences between Member States with regard to the year of birth with the highest percentage of positive cases may be an indication of differences in the period of exposure to the agent and by the effectiveness of measures to prevent transmission of the agent, in particular the feed ban.²⁵

The EU experience shows that the average age of BSE-positive cattle detected in the EU within various targeted risk populations from 2001 and 2007 has progressively increased, e.g., the average age of BSE positive risk animals increased steadily from 88.6 months in 2001 to 131.5 months in 2007.²⁶ Correspondingly, the average age of BSE-positive cattle found in the EU's subpopulation of BSE suspects increased to 148.1 months by 2007.²⁷

In stark contrast, however, the Canadian experience shows no comparable trend. Instead, and as Chart 1 below shows, the average age of positive Canadian-born BSE cases increased from 2003 to 2007 and *decreased* from 2007 to 2009. Alarming, the average age of Canada's BSE-positive cattle detected in 2008 and 2009 – 76 and 80 months, respectively – reveals that Canadian BSE-positive cattle detected in 2008 and 2009 were on average approximately 4.5 years younger than the average age of BSE-positive cattle detected in risk animals in the entire EU in 2007.²⁸ In addition, Canada's average age of BSE-positive cattle in

²⁴ See 2007 EU Report, at 41.

²⁵ See *id.*, at 45.

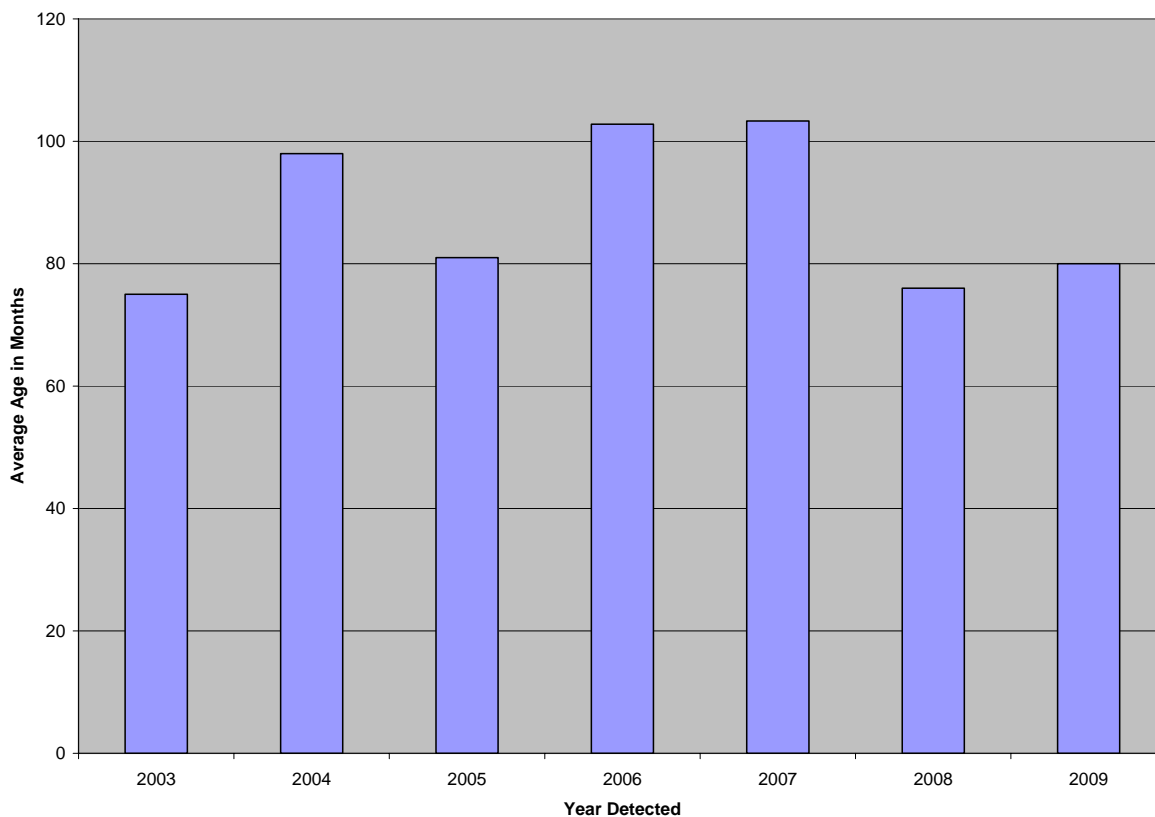
²⁶ See *id.*, at 39.

²⁷ See *Ibid.*

²⁸ See Latest Information, Bovine Spongiform Encephalopathy (BSE) in North America, Canadian Food Inspection Agency (source data for average age of Canadian-born BSE cases), available at <http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbindexe.shtml>; see also 2007 EU Report, at 39 (data source for average age of EU-born BSE cases).

2008 and 2009 was considerably younger than the 121-month average age of BSE-positive cattle detected in risk animals in Poland²⁹ – a country with a total of 55 BSE cases detected since 2003³⁰ – and Poland in 2007 detected a BSE-positive case in a healthy slaughtered animal only 28 months of age.³¹ This discovery raises the legitimate concern that because Canada is detecting BSE in animals that are on average much younger than animals in the EU, it is likely that Canadian cattle have been exposed to higher doses of the BSE agent and are susceptible to BSE even if under 30 months of age, as has now recently been demonstrated in Poland – in a healthy slaughtered animal that would not likely have been detected but for the EU’s mandatory testing program. USDA found that, “Research demonstrates that the incubation period for BSE in cattle is linked to the infectious dose received – i.e., the larger the infectious dose received, the shorter the incubation period.”³² Based on this USDA finding, the younger BSE-positive cattle detected in Canada in 2008 and 2009 likely were exposed to larger doses of BSE infectivity than were available to infect EU cattle in 2007.

Chart 1: Average Age of BSE Positive Cases Detected in Canadian-Born Cattle from 2003 to 2009



Data Source: Canadian Food Inspection Agency

²⁹ See 2007 EU Report, at 39.

³⁰ See *id.*, at 16.

³¹ See 2007 EU Report, at 63.

³² 70 Fed. Reg., at 483, col. 1; see also *id.*, at 512, cols. 1, 2 (“With regard to the possibility that BSE could occur in cattle younger than 30 months of age, research demonstrates that the shorter incubation period (*i.e.*, infection developing in less than 30 months) is apparently linked to younger animals receiving a relatively large infectious dose (Ref 40)”).

Thus, the available data regarding Canada's BSE outbreak, albeit severely limited due to Canada's inadequate testing program, demonstrates that the average age of BSE positive cattle in Canada is *not* progressively increasing over time – indicating that Canada's mitigation measures have *not* been effective in decreasing the prevalence of BSE in younger Canadian animals. And, a comparison of Canada's average age of BSE-positive cattle with that of the EU's demonstrates that Canada's BSE evolution is *not* following the more favorable European trend associated with an apparent decrease in BSE prevalence. The U.S. Centers for Disease Control and Prevention ("CDC") has recently updated its assessment of BSE cases identified in Canadian-born cattle and stated:

As of May 2009, 17 BSE cases in Canadian-born cattle have been identified, 16 in Canada and 1 in the United States. Eleven of these 17 BSE cases were known to have been born after the implementation of the 1997 Canadian feed ban; ten of these eleven were born after March 1, 1999. [] This latter date is particularly relevant to the United States because since a USDA rule went into effect on November 19, 2007, Canadian cattle born on or after March 1, 1999, have been legally imported into this country for any use. One of the 16 Canadian-born BSE cases was reported in an animal that was most likely born before or possibly very shortly after implementation of the 1997 feed ban. Based on the known or most likely year of birth, an average of 1.3 cases of BSE occurred among the group of animals born each year in Canada from 1991 through 2003. The highest reported number of cases by birth year in a single year, 3 BSE cases, occurred in 2000, 2001 and 2002.³³

The foregoing discussion reveals that the critical assumptions relied on by USDA to justify its OTM Rule are completely baseless. USDA's 2007 assumption that the prevalence of BSE in Canadian cattle will decrease over time is now contradicted by empirical evidence;³⁴ the agency's 2007 assumption that the Canadian feed ban "has been effectively enforced" since March 1, 1999, is now contradicted by empirical evidence;³⁵ and USDA's assumption that Canadian cattle born after 1998 would not likely be exposed to the BSE agent is now contradicted by empirical evidence.³⁶ Most importantly, the critical assumption USDA used to propel its Minimal Risk Region Rule ("MRR Rule"), upon which its OTM Rule is based, and then to defend its MRR Rule before the 9th U.S. Circuit Court of Appeals – that "[c]ows in Canada can be expected to have a longer incubation period [than cows in England] because of their significantly lower levels of BSE exposure" – is now proven absolutely false by empirical evidence.³⁷

³³ BSE (Bovine Spongiform Encephalopathy, or Mad Cow Disease), Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, available at <http://www.cdc.gov/ncidod/dvrd/bse/index.htm>.

³⁴ See 72 Fed. Reg., at 53334, col. 1.

³⁵ See *id.*, at 53327, col. 3.

³⁶ See 72 Fed. Reg., at 1123, col. 2.

³⁷ Order and Amended Opinion, *Ranchers-Cattlemen Action Legal Fund v. United States Dept. of Agriculture*, 9th Circuit Court of Appeals, 05-35264, D.C. No. CV 05-006 RFC, Amended August 17, 2005, at 10847; see also *id.*, at 10841 ("Based on Canada's low BSE rate and its feed ban, Canadian cattle should have a much lower exposure than English cattle, resulting in a correspondingly greater incubation period.").

USDA cannot allow its OTM Rule to stand as it clearly is a house of cards that is not supported by scientific evidence. The OTM Rule is exposing U.S. consumers and the U.S. cattle herd to an unacceptable level of BSE risk that is now shown by available data to be even higher than the BSE risk in the EU.

III. CONCLUSION

R-CALF USA appreciates the opportunity to provide these third supplemental comments regarding the OTM Rule to USDA. We urge USDA to immediately abandon its previous practice of exposing U.S. consumers and the U.S. cattle herd to increased risk for BSE based on unsupported and unequivocally erroneous assumptions. Instead, USDA must quickly and decisively restore the previously dismantled import protections that once prevented the introduction of BSE into the U.S. from Canada. The first essential step that USDA must take is to withdraw, in its entirety, the OTM Rule. Once this is accomplished, USDA should initiate discussions with Canadian animal health officials to urge them to implement a mandatory testing program sufficiently robust to enable an accurate assessment of Canada's BSE evolution and the effectiveness, or lack thereof, of its BSE mitigation measures. Until the OTM Rule is withdrawn, however, USDA is irresponsibly subjecting U.S. consumers and the U.S. cattle herd to an unacceptable risk for an invariably fatal and incurable disease that the agency has both the duty and authority to avoid.

Sincerely,

A handwritten signature in cursive script that reads "R. M. Thornsberry D.V.M." with a small flourish at the end.

R.M. Thornsberry, D.V.M.
President, R-CALF USA Board of Directors

Attachment A